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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,568	02/18/2004	Edouard Koullick	539.5005.1	9297

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INTELLECTUAL PROPERTY GROUP
FREDRIKSON & BYRON, P.A.
200 SOUTH SIXTH STREET
SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/781,568

Applicant(s)

KOULLICK ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 6, 7, 11-18, 20, 23, 24, 28-32, 34, 37, 38, 42-50, 52, 55, 56, 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,008,397 to Tweden in view of US 6,110,155 to Baudino.

In the specification and figures, Tweden discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 32, and 50, Tweden discloses a medical shunt in the shape of a hollow cylinder 20, forming a conduit 12 therein (see column 3, lines 60-67). The conduit has open ends 28, 30 that receive and discharge body fluids (see column 4, lines 1-9). The shunt may comprise occlusion-resistant materials deployed in a delivery agent (such as a knitted cloth) that resist occlusion of the shunt (see column 1, lines 43-54, column 17, lines 50-60). (With specific regard to claims 32 and 50, see columns 15-17 for Tweden's disclosure of preparing or making the disclosed shunt, column 18 for Tweden's disclosed method of inhibiting occlusion by implanting the shunt and allowing the drugs to elute from the shunt.)

Tweden fails to disclose that the hunt comprises a plurality of apertures at the proximal end of the shunt or that the occlusion-resistant materials may be located on

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the internal surface of the tube. However, Baudino discloses a catheter comprising a conduit 14 with a plurality of apertures 32 at the distal end to improve fluid flow between the lumen 20 and the outside of the catheter (see FIG 2, column 3, lines 20-30).

Furthermore, Baudino discloses that the catheter 14 may comprise a medicament that is dispersed throughout the polymeric catheter, allowing the medicament to diffuse into the patient from the interior and exterior of the catheter, preventing inflammation and blockage both inside and outside the catheter (see column 3, line 45 to column 4 line 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Tweden with proximal apertures and medicaments on the interior of the shunt, as disclosed by Baudino, in order to improve fluid flow and prevent inflammation, as taught by Baudino.

With regard to claims 3, 20, 34, and 52, Tweden discloses that the shunt may be made of a low-density polyethylene (see column 4, lines 50-55).

With regard to claims 6, 23, 37, and 55, Tweden discloses that the shunt may incorporate anticoagulants (see column 7, lines 39-40).

With regard to claim 7, 24, 38, and 56, Tweden discloses that the shunt may incorporate compounds containing silver (see column 8, lines 39-40).

With regard to claims 11-13, 16, 42-45, 48, 60-63, and 66, Tweden discloses that the drugs incorporated as a part of the shunt may cover the entire shunt or portions thereof (see column 18, lines 35-38). Tweden's disclosure that a therapeutic agent is in "at least a partial covering" relationship to at least a first portion of the shunt indicates that the therapeutic agent may uniformly cover the entire shunt. Lines 35-48 of column

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18 indicate that different therapeutic materials may be used non-uniformly in different regions of the shunt. (See also Tables 1-3 setting forth the distribution of therapeutic agents in proximal and distal portions of the shunt.)

With regard to claims 14-15, 28, 29, 30, 46, 37, 64, and 65, Tweden discloses that the therapeutic materials may be incorporated in the shunt via various delivery devices and in different amounts in different locations, including a knitted or woven cloth (see column 17, lines 50-60, column 18, lines 35-48).

With regard to claims 17, 31, 49, and 67, applicant's limitations amount to a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Tweden specifically discloses that different therapeutic agents may be deployed on different portions of the shunt. Inherent differences in the physical properties of the therapeutic materials may result in differing release rates between the differing materials. Therefore, the Tweden device meets the limitations of the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 4, 5, 19, 21, 22, 33, 35, 36, 51, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,928,182 to Kraus in view of US 6,110,155 to Baudino.

In the specification and figures, Kraus discloses a shunt comprising a conduit with inflow and outflow ends (see FIG 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (see column 3, lines 15-30, column 6, lines 45-57). Kraus fails to disclose that the shunt comprises various therapeutic materials or proximal apertures. However, Baudino discloses a shunt (see rejection above) that incorporates therapeutic materials in order to resist inflammation and encapsulation (see Baudino column 3, line 45 to column 4 line 7). Baudino further discloses the use of proximal apertures 32 to improve fluid flow between the interior and exterior of the shunt (see column 3, lines 20-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the therapeutic materials and apertures disclosed by Baudino to the shunt disclosed by Kraus in order to resist occlusion of the shunt and improve fluid flow, as taught by Baudino.

5. Claims 8-10, 25-27, 39-41, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,008,397 to Tweden in view of US 6,110,155 to Baudino, further in view of US 2005/0208095 A1 to Hunter et al.

In the specification and figures, Tweden and Baudino disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of incorporating mycophenolic acid as a therapeutic agent within the shunt. With regard to

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claims 8, 9, 25, 26, 39, 40, 57, and 58, Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see, generally, paragraph 0014). In an embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (see paragraph 0223). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Tweden and Baudino with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result, inhibit fibrosis, as taught by Hunter.

With regard to applicant's claims 10, 27, 41, and 59, drawn to a "combination" of mycophenolic acid and another agent, applicant fails to specify the amounts of the combination. A mixture of 100% mycophenolic acid and 0% other agents may comprise a combination, giving the term "combination" its broadest reasonable interpretation.

Response to Arguments

6. Applicant's amendment and arguments filed 21 November 2006 have been entered and been fully considered.
7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

8. With regard to applicant's argument that the Tweden device could not function with the addition of proximal apertures, Examiner asserts that proximal end 30 may comprise apertures that allow for fluid flow into the conduit's interior without leaking fluid to the exterior tissues or otherwise inhibiting the purpose of the Tweden shunt.

9. With regard to applicant's argument that the Tweden disclosure fails to enable the making and usage of several embodiments of the device, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the Tweden disclosure merely suggests the embodiments claimed by applicant, making the instantly claimed invention unpatentable over the prior art of record.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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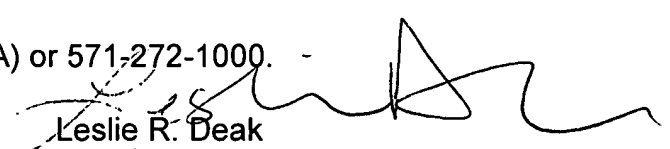
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER



Leslie R. Deak
Patent Examiner
Art Unit 3761
17 January 2007